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EXAMINER

ALAWADI, SARAH

ART UNIT

PAPER NUMBER

1619

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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DETAILED ACTION

Receipt is acknowledged of Applicants amendments/remarks filed on 09/08/2010. The Examiner acknowledges the following:

Claims 1, 3, 6, 8, and 10 are currently amended.

Claim 16 is newly added.

Claims 1, 3-8, 10-12, and 16 are currently under Examination.

WITHDRAWN OBJECTIONS/REJECTIONS

Objection

Claims 1, 6, and 8 are objected to for an inadvertent typographical error. In light of the amendment, said objection is hereby **withdrawn**.

Rejection under 35 U.S.C. 112 second paragraph

Claim 6 is rejected for lack of antecedent basis because part a does not have a first coating. In light of the amendment to the claim, said rejection is hereby **withdrawn**.

Rejection under 35 U.S.C. 102(b)

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al. PCT/GB88/00779. Applicants have amended claim 6 to recite a three layer structure, therefore the rejection is hereby **withdrawn for pending claims 6-7 and cancelled claims 2 and 9 only**, in view of the two distinct layers over the core.

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Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Egidio et al. United States Patent, 5,380,533. Applicants have amended claim 6 to recite a three layer structure, therefore the rejection is hereby **withdrawn for pending claims 6-7 and cancelled claims 2 and 9 only**, in view of the two distinct layers over the core.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-5, 8, and 10-12 **remain** rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al., PCT/GB88/00779.

The Examiner interprets a film forming polymer in light of the specification which can include that of cellulose derivatives, acrylic acid polymers and copolymers, polymers of acrylic acid crosslinked with vinyl glycols and mixtures thereof. Expandable components can include highly swellable grades of cellulose ethers preferably hydroxyethylcellulose, hydroxypropylcellulose, or hydroxypropyl methylcellulose, gums, acrylic acid polymers and copolymers. (MPEP 2111)

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Regarding claims 1, 3-5, 8, and 10-12 Barry et al. teach sustained release of therapeutic agents such as nifedipine. The composition comprises a core of nifedipine (therapeutic) and hydroxypropylmethylcellulose (agent generating internal pressure; expandable component). A coating covering the core comprises water insoluble but swellable acrylic polymers and a hydroxylated cellulose derivative, (expandable components) see abstract. The composition may be in the form of tablets or capsules as the granules are spheronized, see column 7, line 18, page 7 line 30-34 and page 8 lines 1-6. Regarding the limitations wherein the system is capable of instantaneously floating, contains a flotation time of less than 15 minutes, and wherein the film is capable of expanding and maintaining physical integrity in the gastric milieu; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward a necessary property of the composition which is instantly claimed.

RESPONSE TO REMARKS OVER BARRY ET AL.

Applicants argue that Barry et al. does not disclose a specific embodiment in the form of a tablet or capsule which are coated, but rather teaches the coated cores in the form of pellets or granules that are either compressed into tablet or filled into hard gelatin capsules. Applicants argue that Barry does not teach a core in the form of a capsule or a tablet as required by the independent claims.

In response, the Examiner respectfully submits that with regards to independent claims 1 and 8 wherein the gastric retention system is **in the form of** a coated tablet or capsule

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comprising a core in the form of a tablet or capsule, the claim language "in the form of" does not mean that the gastric retention system necessarily **needs to be** a tablet or a capsule, but rather takes the "form" or shape of a tablet or capsule. Barry et al. teach dosage systems in the "form of" tablets and capsules because the coated granules are spheronized in shape, see column 7, line 18 and abstract. Secondly, Barry et al. teaches that the coated granules are placed in capsules comprising a thin gelatin skin coating, see page 7, lines 33.

Secondly, Applicants argue that Barry et al. used low viscosity HPMC which is not a highly swellable polymer in the second or outer coating. For this additional reason, Barry does not anticipate the instant claims.

In response, the Examiner respectfully submits that the claims merely recite that the second or outer coating may comprise highly swellable polymers. Applicant's instant specification discloses that examples of highly swellable polymers include hydroxypropyl methylcellulose, (HPMC) see page 12, line 31 of specification. As the claims are read in light of the specification (per MPEP 2111) and there appears to be no special definition in the specification excluding low viscosity HPMC, as Barry et al. also discloses HPMC in general, it is impossible to ascertain the differences between the HPMC of Barry and Applicants HPMC. Therefore, the claims are read in light of the specification which discloses general HPMC as a highly swellable polymer, and as Barry et al. also teach embodiments with HPMC coatings, the claims remain anticipated.

Claims 1, 3-5, 8, and 10-12 **remain** rejected under 35 U.S.C. 102(b) as being anticipated by Egidio et al. United States Patent, 5,380,533.

The Examiner interprets a film forming polymer in light of the specification which can include that of cellulose derivatives, acrylic acid polymers and copolymers, polymers of acrylic acid crosslinked with vinyl glycols and mixtures thereof. Expandable components can include highly swellable grades of cellulose ethers preferably hydroxyethylcellulose, hydroxypropylcellulose, or hydroxypropyl methylcellulose, gums, acrylic acid polymers, polyethylene glycols (high molecular weight), see page 13-14 of specification. (MPEP 2111)

Regarding claims 1, 3-5-8, 10-12, Egidio et al. teaches pharmaceutical formulations for oral administration which are coated with a gastroresistant film. The formulations include gastroresistant tablets, gastroresistant capsules containing granulates, or soft and hard gelatine capsules containing gastroresistant granulates, see abstract. The first coating (film forming polymer) consists of hydroxypropylmethylcellulose. (highly swellable polymer). Egidio et al. teaches the coating creates a film. (column 4, line 10) The coating substances include hydroxypropylmethylcellulose and methacrylic acid, see claims 1, 2, 5 and 7. The tablets or capsules comprise bile acid (core) and a basic substance, see claim 1. The basic substance includes gas generating agents such as sodium bicarbonates, see claims 1, 2, 5, and 7. The tablet or capsule is coated with a non-protective film which comprises hydroxypropylmethylcellulose (film-forming cellulose derivative) and polyethylene glycol 6000 (swellable polymer)

Regarding the limitations wherein the agent in the core is capable of generating internal pressure on the coat, wherein the expandable components on the tablet core forms a film capable of expanding and maintaining its physical integrity in the gastric milieu; and the flotation time; until

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some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the gastric retention system which is instantly claimed.

RESPONSE TO REMARKS

Applicants argue that the formulation of Egidio et al. is very different from the formulation of the present invention as recited in claims 6 and 16 because in the present invention, the second coating forms a film capable of expanding and maintaining its physical integrity in the gastric milieu which Egidio does not disclose, teach, or suggest. Although Egidio et al. includes a core in the form of a tablet or capsule, Egidio et al. does not disclose an expandable coating as recited in claims 1 and 8. The requirement of an expandable component is a characteristic feature of the present invention which distinguishes the claimed invention from the prior art and may be selected from the group consisting of gas generating agents, highly swellable polymers, superdisintegrants, and mixtures thereof. Egidio et al. is silent with respect to the expandable component.

In response, the Examiner respectfully submits that the components in each layer of Applicants invention are interpreted in light of the specification (MPEP 2111) to include

a) **Film forming polymers:** cellulose derivatives, acrylic acid polymers and copolymers, polymers of acrylic acid crosslinked with vinyl glycols, and mixtures thereof.

b) **Expandable components such as:** hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, gums, acrylic acid polymers and copolymers.

Instant claims 1 and 8 require a gastric retention system **in the form of** a coated tablet or capsule comprising a core in the form of a tablet or capsule comprising an agent **capable of generating internal pressure.** The agent capable of generating internal pressure can comprise highly swellable polymers which per Applicants definition in the instant specification includes that of hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, gums, polyethylene glycols, acrylic acid polymers and copolymers. The tablets or capsules of Egidio et al. comprise bile acid (core) and a basic substance, see claim 1. The basic substance includes gas generating agents such as sodium bicarbonates, see claims 1, 2, 5, and 7. The tablet or capsule is coated with a non-protective film which comprises hydroxypropylmethylcellulose (film-forming cellulose derivative) and polyethylene glycol 6000 (swellable polymer). Regarding the swelling of each polymer, the specification discloses specific swellable polymers (i.e. hydroxypropylcellulose) which are taught by Egidio thus it is expected that the properties of that polymer are such that swelling would necessarily occur. MPEP 2112.01 (II) recites that “products of identical chemical composition can not have mutually exclusive properties. A chemical composition and it’s properties are inseparable.”

Applicants further argue that Egidio is similar to comparative Examples 1 and 2 of the instant application (pages 26-27) which discloses an outer coating with no expandable component and poorly swellable polymers.

In response, the Examiner respectfully submits that comparative Example 1 discloses an outer coating that does not contain any expandable component (i.e. no HPMC). The outer coat of comparative Example 1 does not compare with the embodiments of Egidio as Egidio et al. teaches that the outer coat can comprise hydroxypropylmethylcellulose which is a swellable component as per Applicants definition in the instant specification. With regards to comparative Example 2 which contains HPMC and floats at only 7 hrs, the Examiner respectfully submits table 15 on page 32 discloses alternative embodiments coated with HPMC wherein the tablets float within six minutes. Furthermore, as the composition of Egidio discloses the same ingredients as Applicants absent evidence to the contrary it is expected that the polymers of Egidio (i.e. HPMC) necessarily floats.

NEW REJECTIONS

In light of Applicants amendments, most notably to claims 6 and new claim 16, the following rejections are newly added.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10-12 and newly added claim 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Depui et al. United States Patent 6,365,184.

The claims read on coated tablets comprising a core in the form of a tablet (i.e. shape) comprising an agent which is selected from gas generating agents, highly swellable polymers, superdisintegrants, and mixtures. The coated tablet comprises a first coating comprising an agent which is selected from gas generating agents, highly swellable polymers, superdisintegrants, and mixtures and a second coating which is applied to the first coating comprising film forming polymers and on or more expandable components. Applicant's specification discloses highly swellable polymers include hydroxypropylmethylcellulose, crosslinked polyvinylpyrrolidone, carboxyalkylcellulose, and acrylic acid polymers, see pages 12-13. Examples of film-forming polymers include cellulose derivatives and acrylic acid polymers and crosslinked vinyl glycols

Depui et al. teach formulations in the form of an enteric layer coated tablet, capsule or multiple tablet dosage form, see abstract and figures 1-6. The core material may be mixed with polymers including hydroxypropylmethylcellulose (highly swellable polymer), see column 9, line 13 or cross linked polyvinylpyrrolidone, see column 12, lines 2 and 8-10. The core may be covered with a separating layer which comprises hydroxypropylmethylcellulose (highly swellable), see column 10 lines 1-15. One or more enteric layers may be further applied and include polymers such as carboxymethylethylcellulose (highly swellable) and hydroxypropylmethylcellulose phthalate (film-forming polymer) see column 10, lines 51 and 62. The core (i.e. pellets) may be further covered with an over coating layer. Example 15 discloses an embodiment with a core material comprising hydroxypropylmethylcellulose (highly swellable polymer) and a separating layer of hydroxypropylmethylcellulose (highly swellable polymer)

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The separating layer is further coated with an enteric coating layer which comprises a methacrylic acid copolymer (film former) and polyethylene glycol 6000 (high molecular weight polyethylene oxide swellable polymers).

CONCLUSION

Applicant's amendments are unpersuasive. The amendment and newly added claim 16 necessitated new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678.

The examiner can normally be reached on 9:30 am - 6:00 pm; M-F (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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